UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,879	04/09/2007	**Augustinus Bader**	50326/006001	8676

21559 7590 09/16/2008

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
DEBERRY, REGINA M	
ART UNIT	**PAPER NUMBER**
1647	

NOTIFICATION DATE	DELIVERY MODE
09/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,879	BADER, AUGUSTINUS	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 9-13, 19-22, 31, 34, 36, in part drawn to a method for promoting structural tissue regeneration comprising administering EPO or derivatives, analogues or parts thereof, EMP or NESP, wherein at least some of the process steps are carried out entirely or partly *in vitro*, and a pharmaceutical composition comprising EPO or derivatives, analogues or parts thereof.

Group II, claim(s) 1-6, 9-13, 19-22, 31, 34, 36, in part drawn to a method for promoting structural tissue regeneration comprising administering TPO or derivatives, analogues or parts thereof or DMP, wherein at least some of the process steps are carried out entirely or partly *in vitro*, and a pharmaceutical composition comprising TPO or derivatives, analogues or parts thereof.

Group III, claim(s) 8-13, 20-22, in part drawn to a method for promoting structural tissue regeneration in a patient comprising administering an EPO-inducing factor, wherein at least some of the process steps are carried out entirely or partly *in vitro*.

Group IV, claim(s) 14-18, in part drawn to a method for promoting structural tissue regeneration comprising administering a support structure treated with EPO or derivatives, analogues or parts thereof.

Group V, claim(s) 14-18, in part drawn to a method for promoting structural tissue regeneration comprising administering a support structure treated with TPO or derivatives, analogues or parts thereof.

Group VI, claim(s) 14-18, in part drawn to a method for promoting structural tissue regeneration comprising administering a support structure treated with an EPO-inducing factor.

Group VII, claim(s) 22, in part drawn to a method for treatment of degenerative diseases comprising administering EPO or derivatives, analogues or parts thereof.

Group VIII, claim(s) 22, in part drawn to a method for treatment of degenerative diseases comprising administering TPO or derivatives, analogues or parts thereof.

Group IX, claim(s) 22, in part drawn to a method for treatment of degenerative diseases comprising administering an EPO-inducing factor.

Group X, claim(s) 23-30, in part drawn to the support structure and method of making the support structure comprising EPO or derivatives, analogues or parts thereof.

Group XI, claim(s) 23-30, in part drawn to the support structure and method of making the support structure comprising TPO or derivatives, analogues or parts thereof.

Group XII, claim(s) 23-30, drawn to the support structure and method of making the support structure comprising an EPO-inducing agent.

Group XIII, claim(s) 1, 31-33, in part drawn to a method for promoting structural tissue regeneration comprising administering stem cells and EPO or derivatives, analogues or parts thereof, wherein at least some of the process steps are carried out entirely or partly *in vitro*.

Group XIV, claim(s) 1, 31-33, in part drawn to a method for promoting structural tissue regeneration comprising administering stem cells and TPO or derivatives, analogues or parts thereof, wherein at least some of the process steps are carried out entirely or partly *in vitro*.

Group XV, claim(s) 8, 31-33, in part drawn to a method for promoting structural tissue regeneration comprising administering stem cells and an EPO-inducing factor *in vivo* and/or *in vitro,* wherein at least some of the process steps are carried out entirely or partly *in vitro*.

Group XVI, claim(s) 34 and 35, in part drawn to a pharmaceutical composition comprising stem cells or EPO, derivatives, analogues or parts thereof.

Group XVII, claim(s) 34 and 35, in part drawn to a pharmaceutical composition comprising stem cells or TPO, derivatives, analogues or parts thereof.

The inventions listed as Groups I-XVII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: they lack the same or corresponding special technical features for the following reasons:.

The special technical features are a method for promoting structural tissue regeneration comprising administering a protein, a method for promoting structural tissue regeneration comprising administering a support structure treated with a protein, a method for treating degenerative diseases comprising administering a protein, a method of making the support structure and a support structure and a method for promoting structural tissue regeneration comprising administering stem cells a pharmaceutical composition comprising stem cells. The methods are not required one for the other and/or achieve different goals and thus do not share a common special technical feature. For example, a method for treating degenerative diseases does not share a common special technical feature with a method for promoting structural tissue regeneration. In addition, each method encompasses a diverse methodology and would require its own search of the literature databases. For example administering stem cells *in vivo* would involve different techniques versus administering a protein *in vivo*. In addition, the instant methods and compositions encompass EPO, TPO or EPO-inducing factors. EPO, TPO or EPO-inducing factors do not share a special technical because their sequences bear no resemblance to each other. These very diverse structures result in completely different modes of operation and modes of function and effects.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The protein growth factors recited in claims 9 and 24.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is required to elect ONE growth factor.

The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The protein factors are products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The factors have completely different structures, being made up of completely different building blocks. Furthermore, a search

for one particular factor would not necessarily be co-extensive with a search for a different factor.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does

not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647
9/10/08